

NC Pharmacy Law
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SLIDE 1 TITLE

SLIDE 2

Hello my name is Amanda Fuller Moore. I am the pharmacist in the epidemiology section of the North Carolina Division of Public Health. In this presentation, I am going to review sections of the North Carolina Pharmacy Practice Act related to health departments.

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The learning objectives for this presentation include:

1. Explain the difference between medication administration and medication dispensing
2. Describe the 3 conditions that must be met before a RN may dispense medications
3. Relate the only circumstance that may allow non-pharmacist to dispense medications without meeting the nurse dispensing rules
4. Discuss the purpose of the 340b Drug Program as it relates to STD and TB drugs

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Let's begin with the official definition of administration and dispensing based on the NC Pharmacy practice act.

"Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means.

And

"Dispense" means preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing".

Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing".

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Let's think about this in terms of practical activities. Administration occurs when a patient is given a medication to take immediately, is injected in the clinic by a nurse, or is otherwise provided with a medication that is immediately used by the patient within the clinic.

In contrast to that dispensing occurs when a patient is given a medication that is packaged to take off site, away from the health department to be used later. To think about this and other

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terms, if the patient leaves with the medication in their pocket, in a bottle, in their purse or a bag, in their hand, basically in their possession but not inside the body it is considered dispensing

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Now we are going to move on to looking at nurse dispensing within the local health department. There are three steps that must occur prior to allowing nurse dispensing.

First, the health department must secure the services of a registered pharmacist who will serve as the pharmacy manager and obtain and maintain the pharmacy permit.

Second, training must be provided to nurses in order for them to be qualified as a health department dispensing nurse. This is done by the pharmacist manager.

Third, the pharmacist must report to the health department and retroactively review the dispensing records at least weekly. However if health department nurses collectively dispense to more than 30 patients in a 24 hour period, the pharmacist must verify the accuracy of the dispensing records within 24 hours after the dispensing occurs. As pharmacy manager, the pharmacist is personally responsible for compliance with the NC Pharmacy practice act rules and regulations.

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There are a number of things to keep in mind when looking at developing and maintaining nurse dispensing programs. The ability to dispense within the health department only applies to registered nurses. LPNs and other types of nurses or nurse aides cannot be trained to dispense. A dispensing nurse must be trained by a registered pharmacist. There is an established protocol with the North Carolina Board of Pharmacy and online training materials developed by the North Carolina Division of Public Health to aid pharmacists in the training.

Prescription orders are required for dispensing. Labeling of dispensed medications must meet all requirements outlined in the pharmacy practice act. The person receiving the medication must be a patient of record at the health department.

There is more information on the public health website on nurse dispensing. The website is <http://publichealth.nc.gov/lhd>. Denise Perry, RPh is the contact within the Division of Public health for additional information on nurse dispensing her email address is Denise.perry@wakegov.com.

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Nurse dispensing is limited to medications listed in the pharmacy practice act for specific indications. Those include:

1. antituberculosis medications
2. medications used for STDs as specified by the Centers for Disease Control
3. natural or synthetic hormones or contraceptive devices for the prevention of pregnancy
4. topicals for lice, scabies, impetigo, diaper rash, vaginitis and related skin conditions, and
5. vitamins and minerals.

Again, medications must fall into these categories in order to be permitted under the pharmacy practice act rules for nurse dispensing. The pharmacy practice act specifically prohibits dispensing of controlled substances of any kind through the nurse dispensing program in local health departments.

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Now we are going to switch gears and discuss dispensing medications during emergencies. There is a specific statute within the pharmacy practice act that allows the board of pharmacy to waive portions of the pharmacy practice act in order to permit the provision of drugs, devices and professional services to the public during an emergency. Public Health Preparedness and Response has worked with the Board of Pharmacy to develop a waiver that could be used during events requiring mass dispensing. This waiver could allow for, among other things, those other than a pharmacist or trained nurse dispenser to dispense medications during an emergency.

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Our final topic in this section takes a look at the 340 B medication pricing program. 340B is an agreement between manufacturers to provide discounts for certain entities for outpatient medications. Typically these covered entities would serve vulnerable or underserved patient populations. The way 340 B prices are actually calculated is confidential. However studies have shown that 340 B prices are 25 to 50% below the average wholesale price. The 340 B price of the drug is the lowest price a manufacturer can offer across the board for a medication.

The term covered entity is given to a healthcare facility that qualifies for 340 B pricing. In North Carolina, all local health departments have 340 B accounts for STD and TB medications as well as family planning.

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Here are a few more facts about 340 B:

- You can look up your 340 B ID numbers on the OPA/HRSA database.
- Each 340 B account and contract pharmacy must be individually recertified annually. This means that the 340 B accounts for STD, TB and family-planning must each be re-registered separately annually.
- In order for a covered entity to use 340 B purchased medications the patient being provided the medication must have a relationship with the health department. The easiest way to ensure this is through documentation by making sure that the person has a chart on file in the clinic at the health department.
- Inventories of 340 B medications must be maintained separately for each account and separately from other health department purchased medications.
- The transfer of medications purchased under the 340 B program between covered entities is not permitted. As an example if County A runs out of a medication that County B has in stock, County B cannot provide that medication to County A if it was purchased with the 340 B program.
- For a full summary of the HRSA rules and regulations surrounding the 340 B program, visit www.HRSA.gov\OPA